

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[OAR-2003-0188; FRL-]

RIN: 2060-AI72

**List of Hazardous Air Pollutants, Petition Process, Lesser
Quantity Designations, Source Category List; Petition to
Delist of Ethylene Glycol Monobutyl Ether**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The EPA is amending the list of hazardous air pollutants (HAP) contained in section 112(b)(1) of the Clean Air Act (CAA) by removing the compound ethylene glycol monobutyl ether (EGBE) (2-Butoxyethanol) (Chemical Abstract Service (CAS) No. 111-76-2) from the group of glycol ethers. This action is being taken in response to a petition to delete EGBE from the HAP list submitted by the Ethylene Glycol Ethers Panel of the American Chemistry Council (ACC) (formerly the Chemical Manufacturers Association) on behalf of EGBE producers and consumers. Petitions to delete a substance from the HAP list are permitted under section 112(b)(3) of the CAA.

Based on the available information concerning the potential hazards of and projected exposures to EGBE, EPA

has made a determination pursuant to CAA section 112(b)(3)(C) that there are "adequate data on the health and environmental effects [of EGBE] to determine that emissions, ambient concentrations, bioaccumulation, or deposition of the substance may not reasonably be anticipated to cause adverse effects to human health or adverse environmental effects."

EFFECTIVE DATE: [INSERT DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

ADDRESSES: The EPA has established a docket for this action under Docket ID No. OAR-2003-0188 and A-99-24. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the EPA Docket Center (Air Docket), EPA/DC, EPA West, Room B-102, 1301 Constitution Avenue, NW, Washington, DC 10460. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

The telephone number for the Public Reading Room is (202)566-1744, and the telephone number for the Air Docket is (202)566-1742.

FOR FURTHER INFORMATION CONTACT: Ms. Kelly Rimer, Office of Air Quality Planning and Standards, Emission Standards Division, C404-01, U. S. EPA, Research Triangle Park, NC 27711; telephone number: (919) 541-2962; fax number: 919-541-0840; e-mail address: rimer.kelly@epa.gov.

SUPPLEMENTARY INFORMATION:

Regulated Entities. Entities potentially affected by this action are those industrial facilities that manufacture or use EGBE. The final rule amends the list of HAP contained in section 112(b)(1) of the CAA by removing the compound EGBE. The decision to issue a final rule to delist EGBE removes EGBE from regulatory consideration under section 112(d) of the CAA.

Judicial Review. Under section 307(b)(1) of the CAA, judicial review is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by 60 days from publication in the Federal Register. Under section 307(d)(7)(B) of the CAA, only an objection to a rule or procedure raised with reasonable specificity during the period for public comment can be

raised during judicial review. Moreover, under section 307(b)(2) of the CAA, the requirements established by the final rule may not be challenged separately in any civil or criminal proceeding brought to enforce these requirements.

Outline. The information presented in this preamble is organized as follows:

- I. Introduction
 - A. The Delisting Process
 - B. The Present Petition and Rulemaking
- II. Peer Review of New Data on EGBE Metabolite, Butoxyacetaldehyde
- III. Public Comments on Proposed Rule to Delist EGBE
- IV. Final Rule
 - A. Rationale for Action
 - B. Effective Date
- V. References
- VI. Statutory and Executive Order Reviews
 - A. Executive Order 12866: Regulatory Planning and Review
 - B. Paperwork Reduction Act
 - C. Regulatory Flexibility Analysis
 - D. Unfunded Mandates Reform Act
 - E. Executive Order 13132: Federalism
 - F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
 - G. Executive Order 13045: Protection of Children from Environmental Health & Safety Risks
 - H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
 - I. National Technology Transfer and Advancement Act
 - J. Congressional Review Act

I. Introduction

A. The Delisting Process

Section 112 of the CAA contains a mandate for EPA to evaluate and control emissions of HAP. Section 112(b)(1)

includes an initial list of HAPs that are composed of specific chemical compounds and compound classes to be used by EPA to identify source categories for which EPA will subsequently promulgate emissions standards.

Section 112(b)(2) of the CAA requires EPA to make periodic revisions to the initial list of HAPs set forth in section 112(b)(1) and outlines criteria to be applied in deciding whether to add or delete particular substances. Section 112(b)(2) identifies pollutants that should be listed as: ". . . pollutants which present, or may present, through inhalation or other routes of exposure, a threat of adverse human health effects (including, but not limited to, substances which are known to be, or may reasonably be anticipated to be carcinogenic, mutagenic, teratogenic, neurotoxic, which cause reproductive dysfunction, or which are acutely or chronically toxic) or adverse environmental effects whether through ambient concentrations, bioaccumulation, deposition, or otherwise"

To assist EPA in making judgements about whether a pollutant causes an adverse environmental effect, section 112(a)(7) defines an "adverse environmental effect" as: ". . . any significant and widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or

other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas."

Section 112(b)(3) establishes general requirements for petitioning EPA to modify the HAP list by adding or deleting a substance. Although the Administrator may add or delete a substance on his or her own initiative, the burden is on a petitioner to include sufficient information to support the requested addition or deletion under the substantive criteria set forth in CAA section 112(b)(3)(B) and (C). The Administrator must either grant or deny a petition within 18 months of receipt of a complete petition. If the Administrator decides to grant a petition, the Agency publishes a written explanation of the Administrator's decision, along with a proposed rule to add or delete the substance. If the Administrator decides to deny the petition, the Agency publishes a written explanation of the basis for denial. A decision to deny a petition is final Agency action subject to review in the D.C. Circuit Court of Appeals under CAA section 307(b).

To promulgate a final rule deleting a substance from the HAP list, CAA section 112(b)(3)(C) provides that the

Administrator must determine that there are: ". . . adequate data on the health and environmental effects of the substance to determine that emissions, ambient concentrations, bioaccumulation, or deposition of the substance may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects."

The EPA will grant a petition to delete a substance and publish a proposed rule to delete that substance, if it makes an initial determination that these criteria have been met. After affording an opportunity for comment and for a hearing, EPA will make a final determination whether the criteria have been met.

The EPA does not interpret CAA section 112(b)(3)(C) to require absolute certainty that a pollutant will not cause adverse effects on human health or the environment before it may be deleted from the list. The use of the terms "adequate" and "reasonably" indicate that the Agency must weigh the potential uncertainties and their likely significance. Uncertainties concerning the risk of adverse health or environmental effects may be mitigated if EPA can determine that projected exposures are sufficiently low to provide reasonable assurance that such adverse effects will

not occur. Similarly, uncertainties concerning the magnitude of projected exposure may be mitigated if EPA can determine that the levels which might cause adverse health or environmental effects are sufficiently high to provide reasonable assurance that exposures will not reach harmful levels. However, the burden remains on a petitioner to resolve any critical uncertainties associated with missing information. The EPA will not grant a petition to delete a substance if there are major uncertainties which need to be addressed before EPA would have sufficient information to make the requisite determination.

B. The Present Petition and Rulemaking

On August 29, 1997, the ACC's Glycol Ethers Panel submitted a petition to delete EGBE (CAS No. 111-76-2) from the HAP list in CAA section 112(b)(1), 42 U.S.C. 7412(b)(1). Following the receipt of the petition, we conducted a preliminary evaluation to determine whether the petition was complete according to Agency criteria. To be deemed complete, a petition must consider all available health and environmental effects data. A petition must also provide comprehensive emissions data, including peak and annual average emissions for each source or for a representative selection of sources, and must estimate the resulting

exposures of people living in the vicinity of the sources.

In addition, a petition must address the environmental impacts associated with emissions to the ambient air and impacts associated with the subsequent cross-media transport of those emissions. After receiving additional submittals through December 21, 1998, we determined the petition to delete EGBE to be complete. We published a notice of receipt of a complete petition in the Federal Register on August 3, 1999 and requested information to assist us in technically reviewing the petition.

We received eight submissions in response to our request for comment and information which would aid our technical review of the petition. The comments made general statements encouraging EPA to delist EGBE. None of the comments included technical information.

On November 4, 2003, based on a comprehensive review of the data provided in the petition and otherwise provided to EPA, the Agency made an initial determination that the statutory criteria for deletion of EGBE from the HAP list had been met. The EPA, therefore, granted the petition by the ACC's Glycol Ethers Panel and issued a proposed rule to delist EGBE (68 FR 65648, November 21, 2003).

The EPA received a total of 18 comments on the November

21, 2003 proposed rule. While three of the commenters opposed deleting EGBE from the HAP list, they provided no substantive arguments to support this position. There was no request for a public hearing.

The EPA's decision to remove EGBE from the list of HAP is based on the results of a risk assessment demonstrating that emissions of EGBE may not reasonably be anticipated to result in adverse human health or environmental effects. In addition to the risk assessment, we have considered public comments, as well as other information related to EGBE in making this decision, namely the transformation of EGBE into other HAP as it decomposes in the ambient air. We conclude that ambient concentrations of the transformed HAP are very small, and that they decompose rapidly. Therefore, we do not anticipate that EGBE transformation will be significant enough to have an adverse impact on human health.

We also considered the fact that EGBE is reported to the Toxics Release Inventory (TRI) as part of the group of glycol ethers. The 2000 TRI shows the air emissions of the class of chemicals "Certain Glycol Ethers" to be ranked number 12 by volume. Under the final rule, it will no longer be regulated as a HAP, but it will continue to be

reported in the TRI, as part of the group "Certain Glycol Ethers" and regulated under EPA's criteria pollutant (ozone) program.

The EPA has made a final determination, after careful consideration of the petition and after completing additional analyses, that there are adequate data on the health and environmental effects of EGBE to determine that emissions, ambient concentrations, bioaccumulation, or deposition of EGBE may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects.

II. Peer Review of New Data on EGBE Metabolite, Butoxyacetaldehyde

In the preamble to the proposed rule, we stated that the Agency believes EGBE is not genotoxic and that two distinctly different nonlinear modes of action are principally responsible for the increased forestomach and liver tumors reported by NTP (2000a). These modes of action are discussed in detail in the Interim Final position paper, "An Evaluation of the Human Carcinogenic Potential of Ethylene Glycol Butyl Ether," available from the Docket for the final rule. We also stated that there are reports of weak positive effects by EGBE at high concentrations in some

in vitro assays which may indicate the potential for genotoxicity by butoxyacetaldehyde (BAL), an EGBE metabolite known to cause clastogenic changes at high in vitro concentrations (see the section on ``Other Possible Modes of Action for Forestomach Tumor Development in Female Mice'' in the Agency's position paper). However, available evidence from a published EGBE physiologically based pharmacokinetic model that had been modified to include kinetics for the metabolism of the BAL intermediate (Corley, 2003) suggested that the concentrations of BAL metabolite predicted to occur in vivo would be much lower than the concentrations used in the in vitro assays. Based on this, it appears that genotoxicity is not a factor in tumor development in female mice. This increases our confidence that a nonlinear mechanism is involved in tumor formation (versus a linear mechanism which would be suggested if genotoxicity was involved). As we discussed in the preamble to the proposed rule, additional research (e.g., verification of these PBPK modeling results and further genotoxicity research using more appropriate assays and currently accepted test protocols) would be beneficial to provide a more definitive determination regarding the role of BAL in the formation of forestomach tumors in female mice.

Since the publication of the proposed rule, additional research has been completed and submitted to EPA. Subsequently, we commissioned a peer review panel to evaluate the new data submitted and EPA's conclusions of the proposed ruling and interim final position paper in light of the recent research and literature that has been submitted to the Agency in response to the Agency's proposed EGBE ruling. The peer review was conducted on May 19, 2004 by an external review panel of seven experts. A report on the results of this peer review is included in the docket for the final rule. In summary, the peer review panel was unanimous in agreeing that there is enough information to support an informed decision concerning the significance of BAL genotoxicity to the formation of EGBE induced liver and forestomach tumors. The available information support a nonlinear mode of action, not a linear mode of action (e.g., genotoxicity) for the male mouse liver tumors and female mouse forestomach tumors observed following EGBE exposure. That is, the reviewers concluded that genotoxicity is not important in the development of these tumors.

The panel also concluded that it is reasonable to expect that a lack of hemolytic effects in humans would preclude the formation of liver tumors in humans and that a

lack of hyperplastic effects in the region of the gastroesophageal junction in humans would preclude the formation of gastrointestinal tumors in humans. That is, the data support the finding that we would not expect to find these tumors in humans following environmental exposures. The RfC and RfD values for EGBE have been set at levels that prevent both the precursor events that would lead to tumors and other noncancer effects, and the Agency has determined that exposures to EGBE are at levels well below the RfC and RfD. We can therefore conclude with confidence that emissions, ambient concentrations, bioaccumulation, or deposition of EGBE may not reasonably be anticipated to cause any adverse effects to the human health.

III. Public Comments on Proposed Rule to Delist EGBE

Of the 18 written comments we received pertaining to the proposed delisting of EGBE, 15 were supportive of the decision to delist and 3 opposed the decision to delist.

The EPA has considered carefully all the comments both supporting and opposing the proposed delisting. A summary of the comments and EPA responses to them has been included in the docket for this proceeding. We received substantive comments with regard to the BAL issue, which we discussed in

detail above. We received no substantive negative comments. Two of the comments in support of the delisting also asked specific policy questions. We respond to those questions below.

Comment: One commenter asked if the rule also applies to diethylene glycol monobutyl ether (DEGBE). The commenter expressed support for delisting both chemicals in the rule.

Response: The final rule applies only to EGBE, one of the compounds included in the group of glycol ethers listed in the section 112(b)(1) HAP list. The petition requested that one single compound, EGBE, be delisted; it did not request EPA to consider removing any other compounds in the group of glycol ethers. Therefore this action pertains only to EGBE.

Comment: One commenter urged EPA to address the "Once In, Always In" policy in the final rulemaking for facilities that will no longer be major sources for MACT standards once EGBE is delisted. This commenter requested that the "Once In, Always In" policy not apply to delistings in general, since a facility that was only over the major source threshold due to emissions of a subsequently delisted HAP may never have been a "major source" from a health perspective, and therefore never really "in". The commenter

argued that the purpose of the policy that sources not be allowed to backslide from MACT standards, is not applicable to delistings because in such cases the health and environmental protection of a standard is not undermined since the delisted chemical has been determined not to be a health and environmental threat.

Response: This action addresses a request to remove a specific pollutant from the HAP list. Any questions about the "Once In Always In Policy" are beyond the scope of today's action. The EPA will address the "Once In Always In Policy" in the future.

IV. Final Rule

A. Rationale for Action

The detailed factual rationale for supporting the Agency's initial determination that the criteria in Clean Air Act section 112(b)(3)(C) had been met is set forth in the proposed rule published in the Federal Register on November 21, 2003 (68 FR 65648). However, as described above, EPA received additional data during the public comment period and had those data peer reviewed. The results of the peer review strengthen the case for delisting. The EPA also received 18 public comments on the proposed rule, none of which caused EPA to revise the

scientific basis upon which the initial determination to delist EGBE was predicated. The EPA hereby incorporates into its rationale for the final rule the substantive assessment of potential hazards, projected exposures, human risk, and environmental effects set forth in the proposed rule to delist EGBE. Based on that assessment, the Agency's evaluation of the comments, and additional information submitted during the rulemaking (as summarized above), EPA has made a determination that there are adequate data on the health and environmental effects of EGBE to determine that emissions, ambient concentrations, bioaccumulation, or deposition of the compound may not reasonably be anticipated to cause adverse human health or environmental effects.

B. Effective Date

The final rule will be effective on [INSERT DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER], the date it is published in the Federal Register. Although Section 553(d) of the Administrative Procedures Act, 5 U.S.C. 553(d), provides that substantive rules must be published at least 30 days prior to their effective date, this requirement does not apply to this action. First, the rule was promulgated pursuant to CAA section 307(d), and that provision expressly states that the provisions of

section 553 do not apply to this action. Second, even under section 553, the requirement that a rule be published 30 days prior to its effective date does not apply to a rule, "which grants or recognizes an exemption or relieves a restriction."

V. References

References cited in the preamble can be viewed in the docket for the final rule.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), EPA must determine whether the regulatory action is "significant" and therefore subject to Office of Management and Budget (OMB) review and the requirements of the Executive Order. The Executive Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of \$100 million or more or adverse affect in a material way the economy, a sector to the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities;

(2) create a serious inconsistency or otherwise

interfere with an action taken or planned by another agency;

(3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligation of recipients thereof; or

(4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

Pursuant to the terms of Executive Order 12866, it has been determined that the final action does not constitute a "significant regulatory action" and is, therefore, not subject to OMB review.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. The final action will remove EGBE from the CAA section 112 (b)(1) HAP list and, therefore, eliminate the need for information collection under the CAA. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and

verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

C. Regulatory Flexibility Act (RFA)

The RFA generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small business, small organizations, and small governmental jurisdictions. For the purposes of assessing the impacts of today's final rule on small entities, small entity is defined as: (1) a small business

that meets the definitions for small business based on the Small Business Association (SBA) size standards which, for this final action, can include manufacturing (NAICS 3999-03) and air transportation (NAICS 4522-98 and 4512-98) operations that employ less 1,000 people and engineering services (NAICS 8711-98) operations that earn less than \$20 million annually; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impact of today's final rule on small entities, I certify that this final action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analysis is to identify and address regulatory alternatives "which minimize any significant economic impact of the final rule on small entities." (5 U.S.C. 603 and 604). Thus, an agency may

certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. The final rule will eliminate the burden of additional controls necessary to reduce EGBE emissions and the associated operating, monitoring and reporting requirements. We have, therefore, concluded that today's final rule will relieve regulatory burden for all small entities. We continue to be interested in the potential impacts of the final rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 1044, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for final and final rules with "Federal mandates" that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any 1 year.

Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's final rule contains no Federal mandates for

State, local, or tribal governments or the private sector. The final rule imposes no enforceable duty on any State, local or tribal governments or the private sector. The EPA has determined that the final rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. Because the final rule removes a compound previously labeled in the CAA as a HAP, it actually reduces the burden established under the CAA. Thus, today's final rule is not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132, Federalism

Executive Order 13132 (64 FR 43255, August 10, 1999) requires to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Under Executive Order 13132, EPA may not issue a

regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the final regulation. The EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the final regulation.

Today's final rule removes the substance EGBE from the list of HAP contained under section 112(b)(1) of the CAA. It does not impose any additional requirements on the States and does not affect the balance of power between the States and the Federal government. Thus, the requirements of section 6 of the Executive Order do not apply to the final rule.

F. Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable

process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." The final rule does not have tribal implications, as specified in Executive Order 13175. The final rule will eliminate control requirements for EGBE and, therefore, reduces control costs and reporting requirements for any tribal entity operating a EGBE source subject to control under the CAA. Thus, Executive Order 13175 does not apply to the final rule.

G. Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045 (62 FR 19885, April 23, 1997) applies to any rule that: (1) is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

The EPA interprets Executive Order 13045 as applying

only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to influence the regulation. The final rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This determination is based on the fact that the RfC is determined to be protective of sensitive sub-populations, including children.

H. Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211, "Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), requires EPA to prepare and submit a Statement of Energy Effects to the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, for certain actions identified as "significant energy actions." The final rule is not a "significant energy action" because it is not likely to have a significant adverse effect on the

supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

Section 112(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104-113, section 12(d) 915 U.S.C. 272 note), directs all Federal agencies to use voluntary consensus standards instead of government-unique standards in their regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., material specifications, test method, sampling and analytical procedures, business practices, etc.) that are developed or adopted by one or more voluntary consensus standards bodies. Examples of organizations generally regarded as voluntary consensus standards bodies include the American society for Testing and Materials (ASTM), the National Fire Protection Association (NFPA), and the Society of Automotive Engineers (SAE). The NTTAA requires Federal agencies like EPA to provide Congress, through OMB, with explanations when an agency decides not to use available and applicable voluntary consensus standards. The final rule does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing the rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the Federal Register. A major rule cannot take effect until 60 days after it is published in the Federal Register. However, this action is not a major rule as defined by 5 U.S.C. 804(2). The final rule will be effective [INSERT DATE OF PUBLICATION OF THE FINAL RULE IN THE FEDERAL REGISTER].

Delist EGBE from HAP List - Final Rule, Page 30 of 31

List of Subjects in 40 CFR Part 63

Environmental protection, Air pollution control,
Hazardous substances, Reporting and recordkeeping
requirements.

Date

Michael O. Leavitt
Administrator

For the reasons set out in the preamble, part 63, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 63- [AMENDED]

1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401, et seq.

Subpart C-[AMENDED]

2. Subpart C is amended by revising §63.63 to read as follows:

§63.63 Deletion of ethylene glycol monobutyl ether from the list of hazardous air pollutants.

The substance ethylene glycol monobutyl ether (EGBE, 2-Butoxyethanol) (CAS Number 111-76-2) is deleted from the list of hazardous air pollutants established by 42 U.S.C. 7412(b)(1).